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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/701,038 | 11/04/2003 | Jere W. McBride | D6481 | 9804 |

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| EXAMINER | |
|---|---|
| ZEMAN, ROBERT A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/701,038 | MCBRIDE ET AL. | |
| | Examiner | Art Unit | |
| | Robert A. Zeman | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to nucleic acids encoding *Ehrlichia canis* p153 proteins having the amino acid sequence of SEQ ID NO:2, vectors comprising said nucleic acids and host cells comprising said vectors, classified in class 536, subclass 23.7.

II. Claims 6 and 15, drawn to *Ehrlichia canis* p153 proteins having the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 350.

III. Claims 7-11, drawn to nucleic acids encoding *Ehrlichia chaffeensis* p156 proteins having the amino acid sequence of SEQ ID NO:1, vectors comprising said nucleic acids and host cells comprising said vectors, classified in class 536, subclass 23.7.

IV. Claims 12 and 16, drawn to *Ehrlichia chaffeensis* p156 proteins having the amino acid sequence of SEQ ID NO:1, classified in class 530, subclass 350.

V. Claim13, drawn to antibodies *Ehrlichia canis* p153 proteins having the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 388.4.

VI. Claim 14, drawn to antibodies *Ehrlichia chaffeensis* p156 proteins having the amino acid sequence of SEQ ID NO:1, classified in class 530, subclass 388.4.

VII. Claims 17-20, drawn to methods of determining whether a dog is infected with an *Ehrlichia canis* utilizing *Ehrlichia canis* p153 proteins, classified in class 435, subclass 7.1.

VIII. Claims 17-19, drawn to methods of determining whether a dog is infected with an *Ehrlichia chaffeensis* species utilizing *Ehrlichia chaffeensis* p156, classified in class 435, subclass 7.1.

IX. Claims 21-23, drawn to serodiagnostic kits, classified in class 435, subclass 975.

X. Claims 24-25, drawn to methods of determining whether a dog is infected with an *Ehrlichia canis* species utilizing PCR, classified in class 435, subclass 91.2.

XI. Claims 24-25, drawn to methods of determining whether a dog is infected with an *Ehrlichia chaffeensis* species utilizing PCR, classified in class 435, subclass 91.2.

XII. Claim 26, drawn to PCR kit, classified in class 536, subclass 24.33.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI, IX and XII are separate and distinct from each other, as they comprise differing biochemical and immunological entities having differing properties and uses. In the instant case Invention I and II are drawn to distinct polynucleotides, Inventions III and IV are drawn to distinct proteins and Inventions V and VI are drawn to distinct antibodies.

Inventions VII-VIII and X-XI are separate and distinct from each other as each is drawn to differing methods with differing steps and differing goals and utilizing differing reagents.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used to produce antibodies.

Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention IV can be used to produce antibodies.

Inventions I and III-VI are each separate and distinct from Invention VII, as the compositions of Inventions I and III-VI cannot be used in the methods of Invention VII.

Inventions I-III and V-VI are each separate and distinct from Invention VIII, as the compositions of Inventions I-III and V-VI cannot be used in the methods of Invention VIII.

Because these inventions are distinct for the reasons given above and the search required for the various groups is not coextensive in scope, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday - Thursday 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
December 13, 2004